## HAGENS BERMAN

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June 25, 2013

Martin Kelvas 4065 Rotterdam Pass Hampton, GA 30228

Re: New England Compounding Center Litigation, MDL No. 2419

To Whom It May Concern,

As you are aware, last year New England Compounding Pharmacy, Inc. d/b/a the New England Compounding Center ("NECC") distributed tainted medication to various clinics throughout the country and specifically in Tennessee. Hundreds, if not thousands, of patients have been injured as a result of exposure to tainted NECC products. The most recent Center for Disease Control reports confirm that over 700 patients have confirmed illnesses related to their exposure to tainted NECC pharmaceuticals and over 240 people have confirmed cases of meningitis. Fifty-eight people have died.

The Judicial Panel on Multidistrict Litigation created a multi-district litigation forum in the United States District Court for the District of Massachusetts to address federal lawsuits alleging harm related to products manufactured by NECC (No. 1:13-md-2419-FDS). The Honorable Judge Saylor appointed seven firms to the Plaintiffs' Steering Committee (PSC) and appointed me, Thomas M. Sobol of Hagens Berman Sobol Shapiro LLP, as Lead Counsel.

#### Load Counsel and the PSC are charged with:

- 1. Initiating, coordinating, and conducting all pretrial discovery on behalf of plaintiffs in all actions subject to this order,
- 2. Developing and proposing to the Court schedules for the commencement, execution, and completion of all discovery on behalf of all plaintiffs;
- 3. Issuing in the name of all plaintiffs the necessary discovery requests, motions, and subpoenas concerning any witnesses and documents needed to prepare for the trial of this litigation (similar requests, motions, and subpoenas may be caused to be issued by the PSC upon written request

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by an individual attorney in order to assist him or her in the preparation of the pretrial stages of his or her client's particular claims); and

4. Conducting all discovery, by members or their designees approved by Lead Counsel, in a coordinated and consolidated manner on behalf and for the benefit of all plaintiffs.

NECC has filed for reorganization under Chapter 11 of the Bankruptcy Code. Lead Counsel and the PSC are coordinating their efforts with the Official Creditor's Committee and its counsel, and will share with the Creditor's Committee all appropriate information that you produce in response to the subpoena. The PSC and Lead Counsel are committed to working hand-in-hand with the Official Creditors' Committee. Lead Counsel and the Creditors' Committee will be involved in any settlement discussions.

Lead Counsel and the PSC have designated J. Gerard Stranch, IV of Branstetter, Stranch, and Jennings, PLLC to handle the day-to-day litigation of claims against St. Thomas Outpatient Neurosurgical Center ("STOPNC").

Attached is a subpoena requesting information about your role in STOPNC's purchase, storage, and use of NECC products.

The subpoena requests some information that is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other privacy laws. We have asked Judge Saylor to enter an order in the MDL governing the production of this protected health information (Dkt. Nos. 180-181), and Judge Saylor entered that order on June 21, 2013. (Dkt. No. 192). A copy of this order is attached. Soon, we will identify a HIPAA-compliant vendor to receive (only) protected health information that is responsive to this subpoena. All other responsive information should be produced in accordance with the instructions in the subpoena.

We have also asked Judge Saylor to enter an order confirming that he will centrally enforce all subpoenas and instructing subpoena recipients to file any objections or motions to quash directly into the MDL. (Dkt. No. 182). Judge Saylor entered this order on June 21, 2013. (Dkt. No. 193). A copy of this order is attached. Judge Saylor will hear any objections to the subpoenas at the July 18, 2013 MDL status conference. (Dkt. No. 183).

Thank you. Please contact me or J. Gerard Stranch, IV with any questions.

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Sincerely,

/s/ Thomas M. Sobol

Thomas M. Sobol
Partner
HAGENS BERMAN SOBOL SHAPIRO LLP

TMS:kjp Enclosure

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

All Actions

MDL No. 2419

Master Dkt.: 1:13-md-02419-FDS

### ORDER ON CENTRAL ENFORCEMENT OF SUBPOENAS

WHEREAS the Plaintiffs' Steering Committee has advised the Court that it intends to issue subpoenas to:

- Pain clinics, hospitals, and other entities or individuals who purchased NECC's methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution;
- Vendors and contractors who worked on or were responsible for the conditions of the NECC facility;
- Vendors who conducted sterility or other testing of NECC's products or equipment used to make the products; and
- Suppliers who provided the raw materials used to create methyl prednisolone acetate, cardioplegic solution, or ophthalmic solution.

WHEREAS the Court has the authority to enforce subpoenas issued out of the MDL;

WHEREAS the Court finds that central enforcement of these subpoenas will promote efficiency and the interests of justice;

#### IT IS HEREBY ORDERED

- 1. This Court will centrally enforce subpoenas issued out of the MDL;
- 2. Any objections or motions to quash subpoenas issued out of the MDL shall be filed directly into the MDL. Attorneys are permitted to make a limited appearance for the purposes of contesting a subpoena without being deemed to otherwise consent to the jurisdiction of this Court.

3. Objections to subpoenas served before July 10, 2013 will be heard	during the July
18, 2013 status conference.	
SO ORDERED.	· ·
Dated this 21st day of June, 2013.	
/s/ F. Dennis Sayl	; ,or
F. Dennis Saylor, IV United States District Judge	:

Case 1:13-md-02419-FDS Document 192 Filed 06/21/13 Page 1 of 4

## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No. 2419

Master Dkt.: 1:13-md-02419-FDS

THIS DOCUMENT RELATES TO:

All Actions

# ORDER GRANTING PLAINTIFFS LEAVE TO SERVE SUBPOENAS AND QUALIFIED PROTECTIVE ORDER REGARDING PROTECTION OF HEALTH INFORMATION

WHEREAS, the Court recognizes that protected health information may be produced in response to subpoenas issued by parties in the MDL;

WHEREAS, nothing in this order shall deprive a subpoena recipient of the opportunity to object to requests to produce such protected information;

WHEREAS, the Court desires to establish an up-front process for the production of any such protected health information in compliance with applicable federal and state law.

IT IS HEREBY ORDERED that "Personal Health Information," and "individually identifiable health information" protected under the Health Insurance Portability and Accountability Act of 1996 (hereinafter "HIPAA") (42 USC §1320d et seq.) and the regulations promulgated thereunder (45 CFR §§160, 164 et seq.), shall only be disclosed as follows:

1. Healthcare facilities and/or providers that have examined, tested or treated patients who have been identified as recipients of one or more of New England Compounding Pharmacy, Inc. ("NECC") solutions, medications or compounds, shall produce protected health information pursuant to this order and a subpoena issued by Plaintiffs.

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- 2. The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.
- 3. All protected health information produced pursuant to this order shall be produced in electronic or hard copy format only to a third party vendor (the "Vendor") to be selected jointly by the Plaintiffs' Steering Committee, the chapter 11 trustee appointed in NECC's chapter 11 case (the "Trustee"), and the Official Committee of Unsecured Creditors appointed in NECC's chapter 11 case (the "Official Committee"), after meeting and conferring.
- 4. The Vendor shall hold such protected health information in the strictest confidence and shall not release such information to any other person or entity until further order of this Court.
- 5. In the case of electronic data, the Vendor shall maintain the obtained protected health information on a server that is housed in a data center secured and hardened against unauthorized access or download, including unauthorized access via the Internet or any wireless device. The information obtained in electronic form pursuant to the subpoenas shall be loaded to a database that is password-protected and encrypted. The Vendor shall maintain similar protections against unauthorized access to any protected information produced in hard copy format.

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- The documents, data, or other information produced pursuant to the subpoenas and this Order shall be provided for the sole purposes of (i) investigating, litigating and resolving potential claims involved in this litigation; (ii) litigating and resolving potential claims in the chapter 11 case of NECC (the "Chapter 11 Case"); and (iii) the administration of the Chapter 11 Case, and not for any other purpose. In the event Defendants wish to use documents, data or other information produced pursuant to the subpoenas and this Order, they may seek permission of the Court to do so.
- 7. Within thirty (30) days of entry of this Order, the Plaintiffs' Steering Committee, Defense Liaison counsel, the Trustee, and the Official Committee shall propose to the Court a protocol for sharing the protected health information housed by the Vendor with necessary parties approved by the Court, including without limitation, their experts for purposes of providing expert reports and or analysis. That proposed protocol will also seek to ensure that any such protected health information shared with other parties or experts is provided a level of security against unauthorized disclosure that is compliant with HIPPA.
- 8. Nothing in this Order authorizes direct communications between defendants, their counsel or other agents or representatives and the patients' healthcare providers providing disclosure pursuant to this Order, nor does it bar such communications.
- 9. The Vendor shall maintain the information received in connection with the subpoenas until the later of (i) one (1) year after the resolution of this matter or (ii) one (1) year after the resolution of all claims in NECC's chapter 11 case (in either case, the "Retention Period"), or as otherwise ordered by the Court. At the end of the Retention Period, or as ordered by the Court, it shall destroy any and all originals and copies of the information obtained, including electronic and hard copies.

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10. Plaintiffs' Counsel are authorized to serve subpoenas issued by this Court on the entities listed in NECC's Customer list located at:

http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf as well as Pharmacy Support, Inc., CuraScript, Inc., and Clint Pharmaceuticals.

- All subpoensed entities that provide requested information shall be deemed to fall within the safe harbor of HIPAA for court-ordered production of personal health information, 45 C.F.R. § 164.512(e)(1), and shall have no liability under HIPAA or any other federal or state statute, regulation, or other requirement related to protected health information, for supplying patient or member information to the Vendor.
- 12. The Vendor shall not be deemed to be a guarantor of the completeness and accuracy of the data provided to it and shall have the right to rely in good faith upon the information provided by any subpoensed entity.
- 13. The subpoenzed entities are to use their best effort to supply the requested information.
- 14. The subpoenaed entities must produce the requested information to the Vendor within 30 days of receipt of the subpoena.
  - 15. A copy of this Order shall be appended to the subpoenas.

SO ORDERED.

Dated this 21st day of June , 2013.

/s/ F. Dennis Saylor
F. Dennis Saylor, IV
United States District Judge

AO 88A (Rev. 06/09) Subpoend to Testify at a Deposition in a Civil Action

UNITED STATES DIS	TRICT COURT
for the	
District of Massacht	usetts
In re: New England Compounding Pharmacy, Inc. )  Plaintiff )  v. )	Civil Action No. MDL 1:13-md-02419
Defendant )	(If the action is pending in another district, state where:
SUBPOENA TO TESTIFY AT A DEPOS	ITION IN A CIVIL ACTION
To: Martin Kelvas, 4065 Rotterdam Pass, Hampton, Georgia, 30	228
Testimony: YOU ARE COMMANDED to appear at the deposition to be taken in this civil action. If you are an organization one or more officers, directors, or managing agents, or designate o about the following matters, or those set forth in an attachment:	on that is not a party in this case, you must designate
Place: Mark Zamora and Associates, 6 Concourse Parkway, 22nd Floor, Atlanta, GA 30328	Date and Time: 07/15/2013 9:00 am
The deposition will be recorded by this method: Stenog	raphically and/or Videographically
Production: You, or your representatives, must also bring electronically stored information, or objects, and permit the material:  See Exhibit A	with you to the deposition the following documents, neir inspection, copying, testing, or sampling of the
The provisions of Fed. R. Civ. P. 45(c), relating to your p 45 (d) and (e), relating to your duty to respond to this subpoena at attached.	rotection as a person subject to a subpoena, and Rule and the potential consequences of not doing so, are
Date:06/25/2013	OR A THE STATE OF
Signature of Clerk or Deputy Clerk	Auorney's signature
The name, address, e-mail, and telephone number of the attorney	representing (name of party)
Plaintiffs' Steering Committee  J. Gerard Stranch, IV, Branstetter, Stranch, and Jennings, 227 Sec	, who issues or requests this subpoena, are:

vil Action No. MDL 1:13	3-md-02419		:	
(This secti	PROOF OF SE on should not be filed with the court		P. 45.)	
	(name of individual and title, if any)		:	
as received by me on (date	<del></del>		:	
•	poena by delivering a copy to the nar	ned individual as follows:		
		on (date)	, or	
☐ I returned the su	ibpoena unexecuted because:		: :	
Unless the subpoet tendered to the wit	na was issued on behalf of the United mess fees for one day's attendance, so	l States, or one of its officers or a nd the mileage allowed by law, in	gents, I ha	ve also int of
tendered to the wit	ness fees for one day's attendance, si	nd the mileage allowed by law, i	the amou	int of
tendered to the wit	ness fees for one day's attendance, as	I States, or one of its officers or a nd the mileage allowed by law, in for services, for a total	the amou	ve also ant of 0.00
tendered to the wit  \$  Iy fees are \$	ness fees for one day's attendance, si	nd the mileage allowed by law, in	the amou	int of
tendered to the wit  \$  fy fees are \$  I declare under per	mess fees for one day's attendance, and for travel and \$	nd the mileage allowed by law, in	the amou	int of
tendered to the wit    fy fees are \$  I declare under per	mess fees for one day's attendance, and for travel and \$	nd the mileage allowed by law, in for services, for a total is true.	the amou	int of
tendered to the wit  \$  My fees are \$	mess fees for one day's attendance, and for travel and \$	for services, for a total is true.  Server's signature	the amou	int of

#### Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07).

(c) Protecting a Person Subject to a Subpoens.

- (1) Avolding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction which may include lost earnings and reasonable attorney's fees on a party or attorney who fails to comply.
  - (2) Command to Produce Materials or Permit Inspection.
- (A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
- (B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoens a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
- (i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.
- (3) Quashing or Modifying a Subpoena.
- (A) When Required. On timely motion, the issuing court must quesh or modify a subposen that:
  - (i) fails to allow a reasonable time to comply;
- (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
  - (iv) subjects a person to undue burden.
- (B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:
- (i) disclosing a trade secret or other confidential research, development, or commercial information;
- (ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or
- (iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.
- (C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

- (d) Duties in Responding to a Subpoena.
- (1) Producing Documents or Electronically Stored Information.

  These procedures apply to producing documents or electronically stored information:
- (A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
- (B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
- (C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.
- (D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.
- (2) Claiming Privilege or Protection.
- (A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
  - (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
- (B) Information Produced If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.
- (e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

#### Exhibit A to Subpoena

- 1. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescription order forms, NECP charges for MPA (before and after any discounts applied).
- 2. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
- 3. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.
- 4. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.
- 5. Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage.

- 6. Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other product from NECP during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the amount you paid for the steroid preparation, any discounts you received in purchasing the preparations, applicable warranties, shelf life, expiration dates, prescription order forms, any other account information, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.
- 7. Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between St. Thomas Outpatient Neurosurgical Center, the Howell Allen Clinic, St. Thomas Health, St. Thomas Network, and/or St. Thomas Hospital (collectively the "Healthcare Provider"), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the five-year period immediately preceding October 6, 2012.
- 8. Any and all documents and/or ESI reflecting or containing information obtained by Martin Kelvas and/or the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering and delivery information, company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information)
- 9. Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, Martin Kelvas and/or the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the five-year period immediately preceding October 6, 2012, including but not limited to any microbiology reports or certificates of analysis.
- 10. Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, Martin Kelvas and/or the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.
- 11. Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.
- 12. Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

- 13. Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider or Martin Kelvas pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.
- Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.
- 15. Any and all documents regarding any investigation or inquity the Healthcare Provider or Martin Kelvas performed related to NECP's compliance with UPS 797.
- 16. Any and all documents regarding the Healthcare Provider's and/or NECP's compliance with Tenn. Comp. R. & Regs. R. § 1140-01-.08.
- 17. Any and all documents maintained by the Healthcare Provider related to Tenn. Comp. R. & Regs. R. § 1140-01-04.
- 18. Any and all documents maintained by the Healthcare Provider evincing its compliance with Tenn. Comp. R. & Regs. R. § 1140-01.05 for all NECP products dispensed by the Healthcare Provider.
- 19. Any and all documents showing the names of physicians and/or pharmacists that prescribed and/or dispensed NECP products to patients.
- 20. Any and all documents identifying the names of pharmacists, physicians, nurses, and/or any other healthcare provider that was responsible for purchasing NECP products.
- Any and all documents, correspondence, and/or ESI between Martin Kelvas and any employee, director, officer and/or agent of Howell Allen Clinic related to NECP.
- 22. Any and all documents, correspondence, and/or ESI between Martin Kelvas and any employee, director, officer and/or agent of the St. Thomas Outpatient Neurological Center related to NECP.
- 23. Any and all documents, correspondence, and/or ESI between Martin Kelvas and any employee director, officer, and/or agent of St. Thomas Health.
- 24. Any and all documents, correspondence, and/or ESI between Martin Kelvas and any employee director, officer, and/or agent of St. Thomas Network.

- 25. Any and all documents, correspondence, and/or ESI between Martin Kelvas and any employee director, officer, and/or agent of St. Thomas Hospital.
- 26. Any and all documents, correspondence, and/or ESI between Martin Kelvas and Michael O'neil related to NECP.
- 27. Any and all documents, correspondence, and/or ESI between Martin Kelvas and Dr. John Culclasure related to NECP.
- 28. Any and all documents, correspondence, and/or ESI between Martin Kelvas and Patricia Beckham related to NECP.
- 29. Any and all documents, correspondence, and/or ESI between Martin Kelvas and Debra Shamberg related to NECP.
- 30. Any and all documents, correspondence, and/or ESI between Martin Kelvas and any individual related to the Healthcare Provider's purchase of MPA, cardioplegic solution, ophthalmic solution, and/or preservative-free saline solution.
- 31. Any and all contracts and/or agreements between Martin Kelvas and St. Thomas Outpatient Neurosurgical Center, St. Thomas Hospital, St. Thomas Network, St. Thomas Health, and/or Howell Allen Clinic.